REMARKS

Applicants have reviewed and considered the Office Action dated September 3, 2008, and the references cited therein. In the Action, Claims 21, 22, 24, 26-29, and 32 are rejected under 35 U.S.C. § 102(e) and Claims 23, 25, 30, 31, and 35 are rejected under 35 U.S.C. § 103(a). In view of amendments and the following remarks, Applicant respectfully requests reconsideration and allowance of the pending claims.

Rejections under 35 U.S.C. § 102(e)

Claims 21, 22, 24, 26-29, and 32 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Pub. No. 2004/0078078 (Shepard). Applicant respectfully traverses the rejection for at least the following reasons.

Amended Claim 21 is directed to a spinal bone implant. The implant comprises, in part, "a bore in communication with an outer peripheral surface at the anterior end surface and extending in the region between the inferior and superior surfaces, the bore being at least one of inclined at an angle to the anterior-posterior axis or offset relative to the anterior-posterior axis, and the bore being configured to receive an implant adjustment instrument after the implant has been positioned substantially in the disc space between the respective adjacent vertebrae, and further configured to displace force from the implant adjustment instrument over a relatively wide area of the bore."

Shepard does not disclose, teach, nor suggest a "bore being configured to receive an implant adjustment instrument after the implant has been positioned substantially in the disc space between the respective adjacent vertebrae, and further configured to displace force from the implant adjustment instrument over a relatively wide area of the bore" (emphasis added). Rather, Shepard is directed to a two piece allograft cervical fusion block for use in orthopedic surgical procedures, including one component member of load bearing material, such as cortical bone, and another component member made of cancellous bone. Para. [0021]. A dovetailed recess of the cancellous component receives a dovetailed shape projection of the cortical component to hold the two pieces together. Para. [0061]. Bores with pins inserted therethrough

are provided to increase stability of the graft, and extend through both the cancellous and cortical components. Shepard explains:

> If desired, pins 40 and 42 can be inserted in through going bores 44 and 46 cut through both component members 12 and 30 to increase stability to the graft. The pins 40 and 42 are preferably constructed of cortical bone but can be constructed from any biocompatible material having the necessary strength requirements including metals, plastics compositions and the like and are friction fit in the respective bores 44 and 46. Para. [0063].

In this regard, Shepard discloses bores of varying sizes and configurations which have pins inserted therethough to stabilize the graft. Paras. [0063] – [0069]. However, nowhere does Shepard disclose "a spinal bone implant" having bores which are to remain unfilled, let alone a "spinal bone implant" with a "bore being configured to receive an implant adjustment instrument after the implant has been positioned substantially in the disc space between the respective adjacent vertebrae, and further configured to displace force from the implant adjustment instrument over a relatively wide area of the bore." That is, Shepard discloses bores only for use in conjunction with stabilizing pins. The bores are specifically provided to limit axial and lateral movement of the two-piece fusion block:

> A plurality of bores are cut through the cortical bone member and into the canerous [sic] member to hold pins which are angularly inserted into the bores along opposite sides of the dove tail projection and recess and through the head of the cortical member to limit axial and lateral movement. Para. [0021].

Leaving the bores unfilled, for receipt of an instrument, is not disclosed or suggested by Shepard. Shepard details that the bores receive stabilizing pins to limit axial and lateral movement. Thus, not extending pins through the bores would lead to a less stable implant.

Amended Claim 21 recites "the bore being configured to receive an implant adjustment instrument after the implant has been positioned substantially in the disc space between the respective adjacent vertebrae." Applicant respectfully asserts that even were it proper to ignore the specific teaching of Shepard to insert pins through the bores, the bores of Shepard would not be configured to receive an instrument "after the implant has been positioned substantially in the disc space between the respective adjacent vertebrae." As noted, an implant manufactured in

accordance with Shepard, having bores without pins inserted therethrough, has compromised stability. As discussed at para. [0030] in the present application, the surgeon can use the instrument "to torque and rotate or otherwise reorient the implant to its preferred location." Were the bores of Shepard to receive an instrument, such as for inserting or repositioning the implant, and were that instrument to be used in the way contemplated, the Shepard implant, already in a state of compromised stability, would be subjected to torque and rotation. The Applicants respectfully assert that this would be contrary to the teachings of Shepard.

Indeed, Shepard specifically discusses ways to reorient the implant:

> The cortical front is mated to the cancellous component with the crosspiece inner planar surface being adjacent the cancellous component. The cortical or load bearing component bears not only a compressive load but also serves as an impaction surface. Thus, the surgeon can tap on the anterior cortical surface while impacting the graft without damaging the more brittle cancellous portion of the graft. *Shepard*, para. [0063] (emphasis added).

As is observed from the foregoing, Shepard teaches that a surgeon may orient the bone grafts by tapping the grafts with a suitable instrument, thus eliminating any need for a bore capable of receiving an instrument receiving bore. Such tapping for placement is typical in the art, as discussed at paras. [0026]-[0027] of the present application.

Thus, Shepard teaches inserting stabilizing pins through bores to limit axial and lateral movement. Shepard further teaches that reorientation of the implant may be achieved by tapping on the implant. The Examiner attempts to interpret Shepard in a manner that would provide an implant with bores without stabilizing pins, thus in a compromised state of stability, and insert an instrument through such bores to torque, rotate, or otherwise reorient that implant – notwithstanding Shepard's specific disclosure of manners to reorient the implant that do not torque an implant having compromised stability.

Additionally, nowhere does Shepard disclose, teach, or suggest the bore is "further configured to displace force from the implant adjustment instrument over a relatively wide area of the bore." Applicant respectfully asserts that even were it proper to ignore the specific teaching of Shepard to insert pins through the bores, and in addition use the bores for receiving an implant adjustment instrument, Shepard does not disclose the bores being configured to

displace force from the implant adjustment instrument over a relatively wide area of the bore. In the present application, Applicant points out:

> [D]uring insertion, the vertebrae are bumpy and during insertion the bumps tend to force the implant into undesired orientations. During surgery, the surgeon needs to improvise on this problem and use what ever instruments that may be available for reorienting the implant. Such instruments may be for implant insertion, tamps, curettes, trials, rasps and so on which are designed for specific processing steps and not for orienting the implants. These instruments may, as a result, damage the bone implant, e.g., fracture or splinter it. As recognized by the present inventors, the instruments are not complementary to the implants and also are difficult to use for this purpose because that is not their design function. Para. [0024] (emphasis added).

> It is at this time the surgeon looks around his instrument kit for something to use to reorient the implant, such instruments not being appropriate for such reorientation. Such tools may damage the implant at the bore usually present for an insertion instrument and the implant at the bore is relatively weak. For example, many bone implants in the prior art have bores or recesses used in conjunction with mating insertion implant engagement members or jaws. These bores or recesses may be used by the surgeon for insertion of a non-compatible instrument for reorienting the implant. Such instruments typically subject the implant to possible stress damage to the bone at such weakened locations created by such bores and recesses. The surgeon may insert the instrument into such bore or recess and tap on the instrument with a hammer damaging the implant. Para. [0026] (emphasis added).

> Because of the incompatibility of such instruments with such orienting maneuvers, such tapping introduces additional compressive and/or bending stress forces on the bone at the point of contact, which in practice may be just a contact point, and not a torque spread over an area as desired. The bone may chip or fracture at such stress points. Para. [0027] (emphasis added).

Thus, Applicant discovered a need for a solution to the above problems, particularly a solution for the reorientation of an installed spinal implant in the intervertebral space that will enable a physician to correct for the described mis-orientation of the implant without damage. See, Para. [0028]. Applicant describes in detail, in paras. [0060]-[0068] of the present application, at least one implant embodiment having a bore "configured to displace force from

the implant adjustment instrument over a relatively wide area of the bore" and the structure associated therewith.

The Examiner, in response to Applicant's previous response, notes that the claim language "configured to" is functional language, and in order to be given patentable weight, a functional recitation must be supported by recitation in the claim of sufficient structure to warrant the present of the functional language, citing *In re Fuller*, 1929 C.D. 172; 388 O.G. 279. In contrast, MPEP § 2114 recites "features of an apparatus may be recited either structurally or functionally," but it does go on to say "claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function," citing *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997).

As stated above, Shepard discloses bores with pins inserted therethrough are provided to increase stability of the graft, and extend through both the cancellous and cortical components. It is the Examiner's contention, that even though Shepard nowhere discloses a bore configured to receive an implant adjustment instrument, the bores would be fully capable of receiving an instrument. See, Office Action, pg. 5. Regardless of whether the bores disclosed in Shepard would be fully capable of receiving an instrument, because Shepard does not disclose as such, it does not and cannot disclose a bore "configured to displace force from the implant adjustment instrument over a relatively wide area of the bore," appropriate structure for which is described, for at least one embodiment, in the present application in paras. [0060]-[0068]. Shepard discloses no such structure, explicitly or inherently.

For at least the foregoing reasons, Shepard does not disclose, teach, nor suggest a "bore being configured to receive an implant adjustment instrument after the implant has been positioned substantially in the disc space between the respective adjacent vertebrae, and further configured to displace force from the implant adjustment instrument over a relatively wide area of the bore" (emphasis added), as recited in amended Claim 21.

Therefore Claim 21 is patentably distinguishable from Shepard. Claims 22, 24, 26-29, and 32 depend from Claim 21 and are patentable for the same reasons as Claim 21 and for the additional limitations recited therein.

Rejections under 35 U.S.C. § 103(a)

Claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Shepard in view of US Patent No. 6,261,586 (McKay). Applicant respectfully traverses the rejection for at least the following reasons.

As discussed above, Shepard does not disclose the invention of Claim 21. McKay does not remedy the disclosure deficiencies of Shepard. McKay teaches a spacer for maintaining a space between adjacent bone in a patient including a load bearing body sized and shaped to fit within the space. Col. 10, ll. 40-44. Neither Shepard nor McKay, alone or in combination teach or suggest a "bore being configured to receive an implant adjustment instrument after the implant has been positioned substantially in the disc space between the respective adjacent vertebrae, and further configured to displace force from the implant adjustment instrument over a relatively wide area of the bore," as recited in Claim 21. Claim 23 depends directly from Claim 21. Accordingly, Claim 23 is patentable for at least for the reasons provided above and further in view of its additional recitations. Reconsideration and withdrawal of the rejection of Claim 23 are respectfully requested.

Claim 25 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Shepard in view of US Patent No. 5,766,252 (Henry). Applicant respectfully traverses the rejection for at least the following reasons.

As discussed above, Shepard does not disclose the invention of Claim 21. Henry does not remedy the disclosure deficiencies of Shepard. Henry teaches an interbody spinal prosthetic implant which includes a rigid member having vertically opposite load-bearing surfaces and sides spaced laterally apart. Col. 3, ll. 8-14. Neither Shepard nor Henry, alone or in combination, teach or suggest a "bore being configured to receive an implant adjustment instrument after the implant has been positioned substantially in the disc space between the respective adjacent vertebrae, and further configured to displace force from the implant adjustment instrument over a relatively wide area of the bore," as recited in Claim 21. Claim 25 depends directly from Claim 21. Accordingly, Claim 25 is patentable for at least for the reasons provided above and further in view of its additional recitations. Reconsideration and withdrawal of the rejection of Claim 25 are respectfully requested.

Claim 30 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Shepard in view of US Patent No. 5,554,191 (Lahille). Applicant respectfully traverses the rejection for at least the following reasons.

As discussed above, Shepard does not disclose the invention of Claim 21. Lahille does not remedy the disclosure deficiencies of Shepard. Lahille teaches an intersomatic cage which includes two parallel branches for insertion into vertebral bodies, a linking portion for linking ends of the branches, and a means for angularly spreading ends of the branches after insertion. Col. 1, ll. 54-61. Neither Shepard nor Lahille, alone or in combination, teach or suggest a "bore being configured to receive an implant adjustment instrument after the implant has been positioned substantially in the disc space between the respective adjacent vertebrae, and further configured to displace force from the implant adjustment instrument over a relatively wide area of the bore," as recited in Claim 21. Claim 30 depends directly from Claim 21. Accordingly, Claim 30 is patentable for at least for the reasons provided above and further in view of its additional recitations. Reconsideration and withdrawal of the rejection of Claim 30 are respectfully requested.

Claims 31 and 35 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shepard in view of US Pub. No. 2002/0026242 (Boyle). Applicant respectfully traverses the rejection for at least the following reasons.

As mentioned above, Shepard does not disclose the invention of Claim 21. Boyle does not remedy the disclosure deficiencies of Shepard. Boyle teaches a ramp-shaped intervertebral implant including a body having an opening extending from upper and lower surfaces thereof. Para. [0038]. Neither Shepard nor Boyle, alone or in combination, teach or suggest a "bore being configured to receive an implant adjustment instrument after the implant has been positioned substantially in the disc space between the respective adjacent vertebrae, and further configured to displace force from the implant adjustment instrument over a relatively wide area of the bore," as recited in Claim 21. Claims 31 and 35 depend directly from Claim 21. Accordingly, Claims 31 and 35 are patentable for at least for the reasons provided above and further in view of its additional recitations. Reconsideration and withdrawal of the rejection of Claims 31 and 35 are respectfully requested.

Conclusion

This response is being submitted on or before December 3, 2008, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

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Date: 12/11/08

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